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EXHIBIT 2

CARR ENGINEERING, INC.
12500 CASTLEBRIDGE DRIVE HOUSTON, TEXAS 77065-4532
TELEPHONE 281-894-8955

November 6, 2020

Mr. John Duffy
SWANSON, MARTIN & BELL, LLP
330 North Wabash, Suite 3300
Chicago, IL 60611

Re: In re Pacific Fertility Center

Dear Mr. Duffy,

Carr Engineering, Inc. (CEI) and I have been retained by attorneys representing Chart Inc. entities in the matter referenced above to investigate and analyze the Chart MVE - 808 cryogenic freezer TEC 3000 control system involved in the incident of March 4, 2018 at Pacific Fertility Center (PFC) in San Francisco, California. Specifically, I have focused on the control design, failsafe design, and performance of the TEC 3000 freezer controller as they relate to allegations raised in this matter.

Summary of Opinions

In the course of my investigation, I have been provided with and have considered materials listed in Attachment A and reviewed or generated materials listed in Attachment B. Based upon the materials reviewed and my investigation to date, the details of which are found in this report, I have reached the following opinions to a reasonable degree of engineering certainty:

[redacted]

5. PFC personnel did not notify Chart immediately after the incident on February 15, 2018 resulting in the subject TEC 3000 controller entering a constant state of alarm. Chart would have proceeded with troubleshooting recommendations and service or return procedures if notified by PFC promptly.

6. The manual monitoring method employed by PFC before and after the event with the subject controller on February 15, 2018 was insufficient to accurately monitor and record LN2 usage levels during this period of operation.

Supporting details and bases for each of these opinions can be found in the paragraphs that follow.

Table of Contents

1. Experience and Qualifications to Render Opinions

I am a resident of the State of Texas and an employee of Carr Engineering, Inc., a Texas corporation at 12500 Castlebridge Drive, Houston, Texas 77065. I received my bachelor's degree in Electrical Engineering and a master's degree in Electrical Engineering with emphasis in Control Systems from The Ohio State University in Columbus, Ohio in 1987 and 1991 respectively. I have compiled over 30 years of automotive engineering experience including collegiate co-op assignments prior to 1987 combined with professional employment from 1987 until the present. Over the course of my professional career, I have been involved with areas of algorithm development, software architecture design, countermeasure and diagnostic design, functional safety development, and system engineering requirements management emphasizing controlled brake and controlled suspension products.

From 1987 until 2004, I held several Algorithm Development and System Engineer roles for the Delco Products division of General Motors. This same division later became Delphi Chassis. In these roles I was responsible for the specification, design, evaluation, and testing of multiple vehicle systems including safety, handling, and braking systems, with various levels of integrations with powertrain (engine/transmission) systems and steering systems. During these assignments I gained state-of-the-art experience with electronic sensor processing, diagnostic and countermeasure implementation, serial communications, and control algorithms.

From 2004 until 2016, I held two Engineering Manager positions with Delphi Chassis (later becoming BWI Group, Inc.). The first position I held, from 2004 to 2008, was Manager of the Diagnostics and Communications group. In this role I was responsible for providing technical direction regarding diagnostic algorithms, countermeasure design, serial diagnostic communication protocols, and bootloader flashing methods for core products. My second managerial position, from 2008 to 2016, was that of Manager of the Systems and Software Group. In this capacity, I provided technical direction to the software teams responsible for software implementation within controlled brake products (anti-lock brakes, traction control, and stability control). The software teams under my leadership spanned global locations including Brighton, Michigan; Shanghai, China; and Bangalore, India.

Over the last 10 years, I have developed particular expertise in the areas of functional safety design and the management processes for systems engineering requirements. Since 2008, I have been a member of the U.S. Technical Advisory Group responsible for the development of the ISO-26262 functional safety standard for road vehicles. Managing the development of production embedded software for Delphi's safety systems also required me to become well versed in industry methods such as ASPICE (Automotive Software Process Improvement and Capability dEtermination) along with various disciplines of systems engineering to effectively specify, communicate, implement, and verify requirements.

Since February 2016, I have been employed as a Principal Engineer at Carr Engineering, Inc. In this role, I rely on my 30+ years of industry experience to perform investigations to determine the causes, conditions, and circumstances of defect allegations related to all forms of embedded system design, not just those specifically found in automotive microprocessors. Regardless of the application, I am able to analyze claims pertaining to embedded system design, countermeasure strategy, software implementation, and fault analysis. In the

automotive context, this includes emerging technologies such as advanced driver assistance system (ADAS) features, autonomous driving technologies and their derivatives, and cybersecurity matters.

Throughout my professional career I have published and presented material related to my work as an engineer. This effort began in 1991 with my master's thesis, "A DSP Hybrid Simulator For Evaluating Anti-Lock Brake System Control Design" and has continued to the present. I have authored and co-authored several SAE papers in my area of expertise and have been invited to present at several technical conferences focusing in the areas of functional safety and software development. In addition to publishing and presentation, I have been awarded several U.S. Patents in these same areas, and have been the recipient of two GM Boss Kettering Awards: Automotive Chassis Control – Integrated Chassis (1996) and Unified Brake and Suspension Control (2000).

Carr Engineering, Inc. charges $395 per hour for my services. Copies of my current CV and testimony list can be found as Attachments C and D respectively.

2. Plaintiff Complaint and Allegations

I have reviewed the 3rd Amended Complaint filed by the Plaintiffs in this matter relating to the incident at PFC on March 4, 2018. In the complaint, the Plaintiffs allege that the TEC 3000 controller "malfunctioned shortly before the incident" and that "To the extent this malfunctioning controller contributed to the harm suffered by Plaintiffs, Chart is responsible for that as well."

Plaintiffs allege that Chart was negligent because "Chart should have recalled or retrofitted all tanks equipped with a TEC 3000 electronic control system prior to March 4, 2018." For support, Plaintiffs allege that the TEC 3000 controller "was prone to malfunction, leading to inaccurate measurements and false alarms" and that Chart knew or it was reasonably foreseeable that "customers would continue to use their cryogenic freezers without a fully functional controller."

I have considered these and other related allegations in my investigation of the TEC 3000 controller. I disagree that anything Chart did, or did not do, involving the TEC 3000 controller was negligent or caused or contributed to the alleged injuries. The TEC 3000 controller was not dangerous or likely to be dangerous when used in a reasonably foreseeable manner.

3. Incident Overview

I have reviewed materials received which provide an account of the incident at the Pacific Fertility Center. The PFC response to the College of American Pathologists (CAP) report [MSO001982 – MSO001991] states that PFC staff became aware of a loss of LN2 and failure of the Tank 4 system on Sunday March 4, 2018, approximately 12:30 p.m., during a routine check of the storage tank. PFC staff immediately took action to first replenish the LN2 in the failing tank, and then prepare the facility's backup tank for sample transfer.

[redacted]

[redacted]

[redacted]

4. Testimony Statements

To understand the Chart MVE-808 freezer development, operation, and distribution I have reviewed more than 43 depositions from Chart, Extron and PFC employees, PFC clients and investigating experts. I have referenced depositions statements below from PFC staff Dr. John Conaghan and Ms. Gina Cirimele to provide insight on how the MVE-808 freezer and TEC 3000 controller were used at PFC leading up to events of February 15 and March 4, 2018.

4.1 Dr. Joseph Conaghan

Dr. Joseph Conaghan, PFC Lab Director, was deposed on August 31, 2020. In his deposition Dr. Conaghan acknowledged "…a normal controller is capable of measuring the level of liquid inside the tank, and the controller is also capable of calculating usage of nitrogen inside the tank." However, when asked how often he would check the liquid nitrogen usage rate of Tank 4 leading up to the incident, he responded, "We didn't check usage."

[redacted]

4.2 Ms. Gina Cirimele

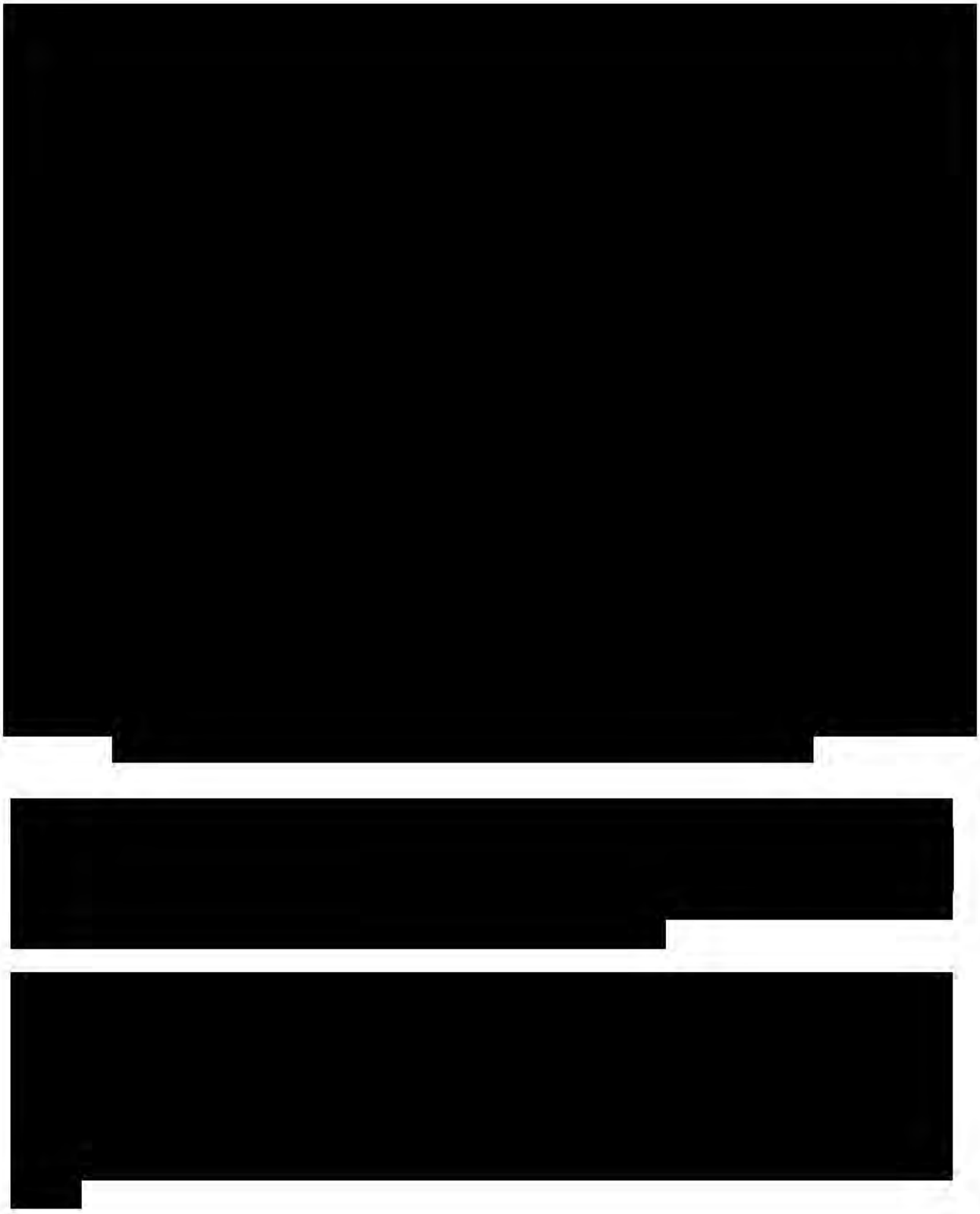
Ms. Gina Cirimele, PFC Embryologist, was deposed on August 31, 2020. In her deposition Ms. Cirimele described the normal measurement process on Tank 4 by stating, "We would read the level of the liquid nitrogen from the controller. …We would record it in our QC log." Further Ms. Cirimele determined the need to fill the freezer with LN2 by noting, "The level on the controller would be lower, at a lower range." Ms. Cirimele confirmed that she would record the liquid nitrogen level after completing the fill cycle. When asked where the LN2 measurements were recorded Ms. Cirimele responded, "We record the(m) manually in a

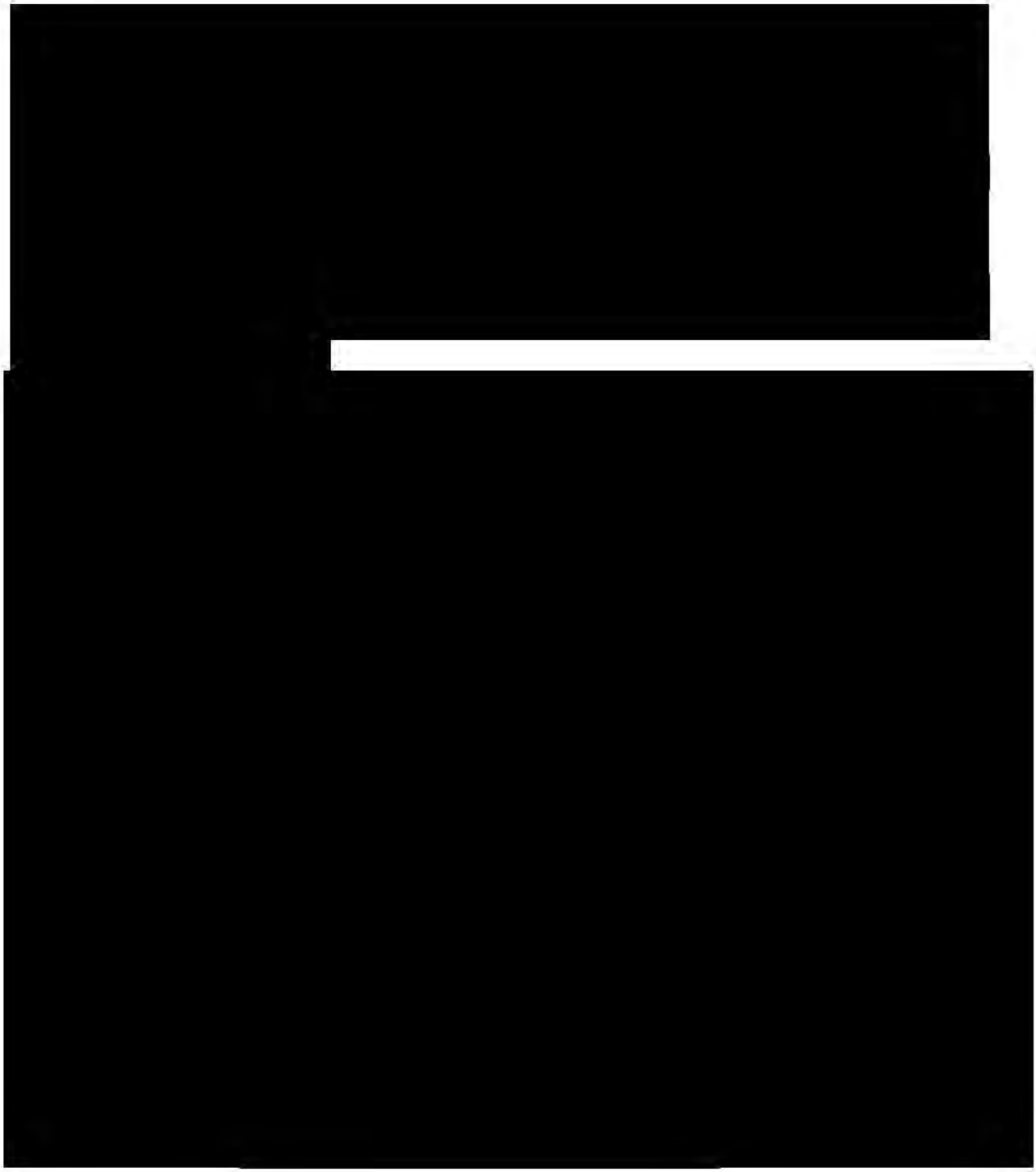
logbook". She confirmed that now the process is to input measurements into the Reflections program.

Ms. Cirimele acknowledged when asked "Has anyone ever forgotten to enter data at Pacific Fertility and then had to go back and put it in?" …"Yes, So if a value was not entered at the end of the day we would go back and look at our hard copy paper log and fill it in from that. So it was written down especially in that period of time of doing recording when you were first starting Reflections, some values would be forgotten to be put in. So we would go back and enter in the forgotten value or the missed value for the day."

When asked "In any of your jobs, have you ever been trained how to calculate liquid nitrogen consumption?" Ms. Cirimele responded, "Not before the incident." When asked to describe the LN2 fill point after the controller stopped working properly in February of 2018, Ms. Cirimele responded "We have a range that we would use. It wasn't the specific point that the controller had."

Ms. Cirimele confirmed that the Tank 4 controller was connected to a Sensaphone device and that the Sensaphone would call a cell phone and issue a text if an alarm condition was observed.





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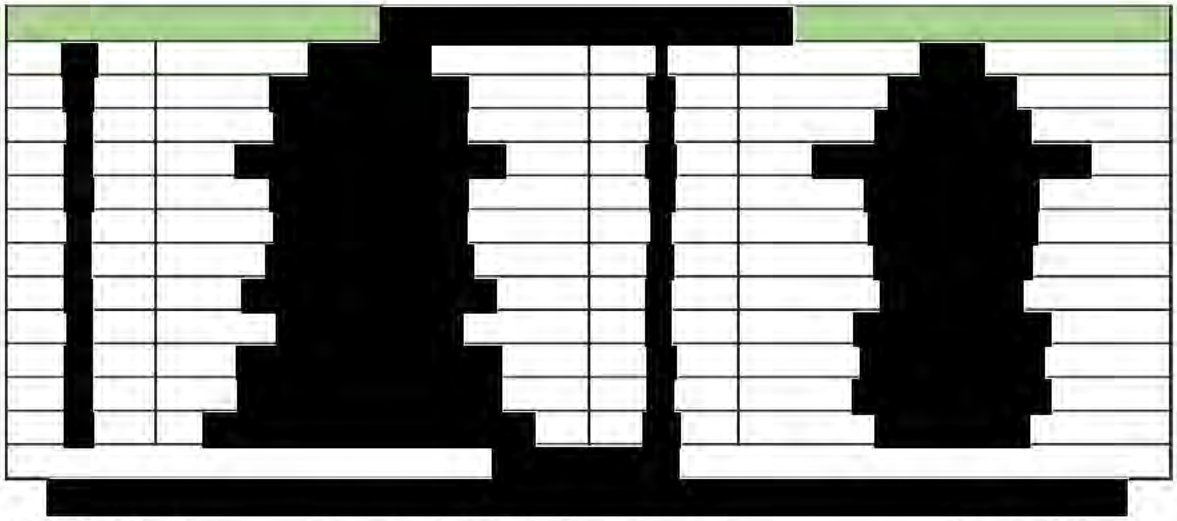

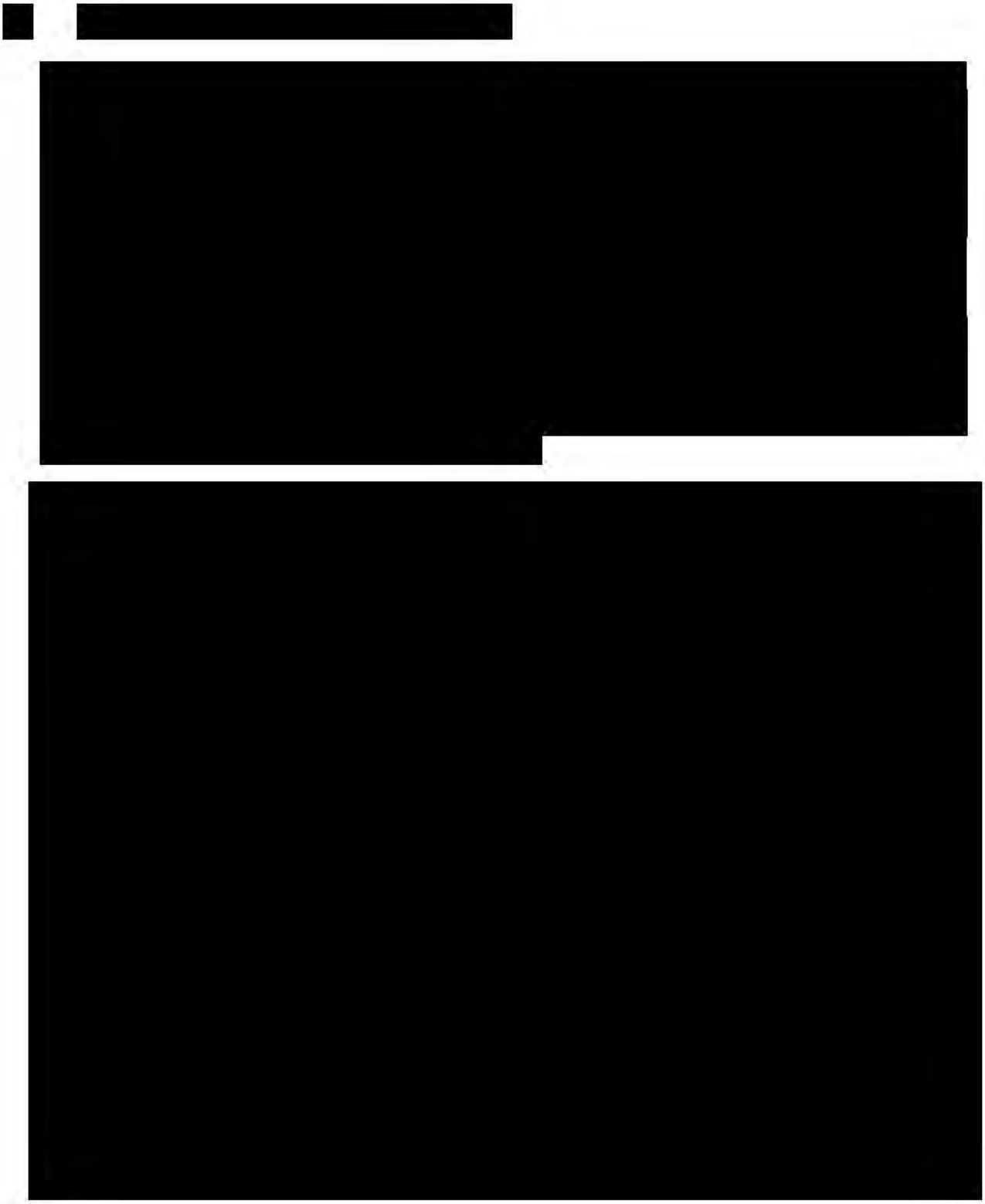

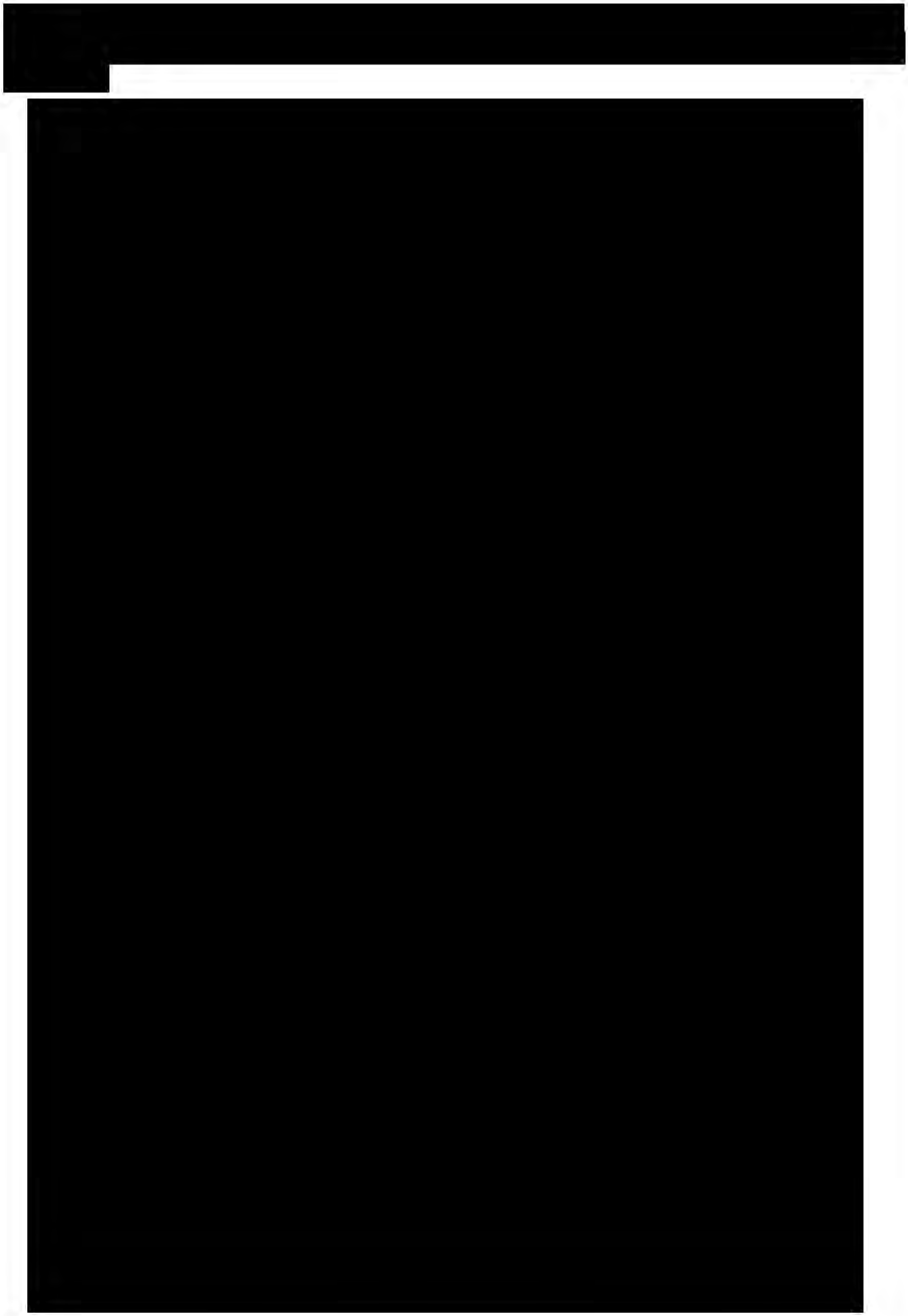

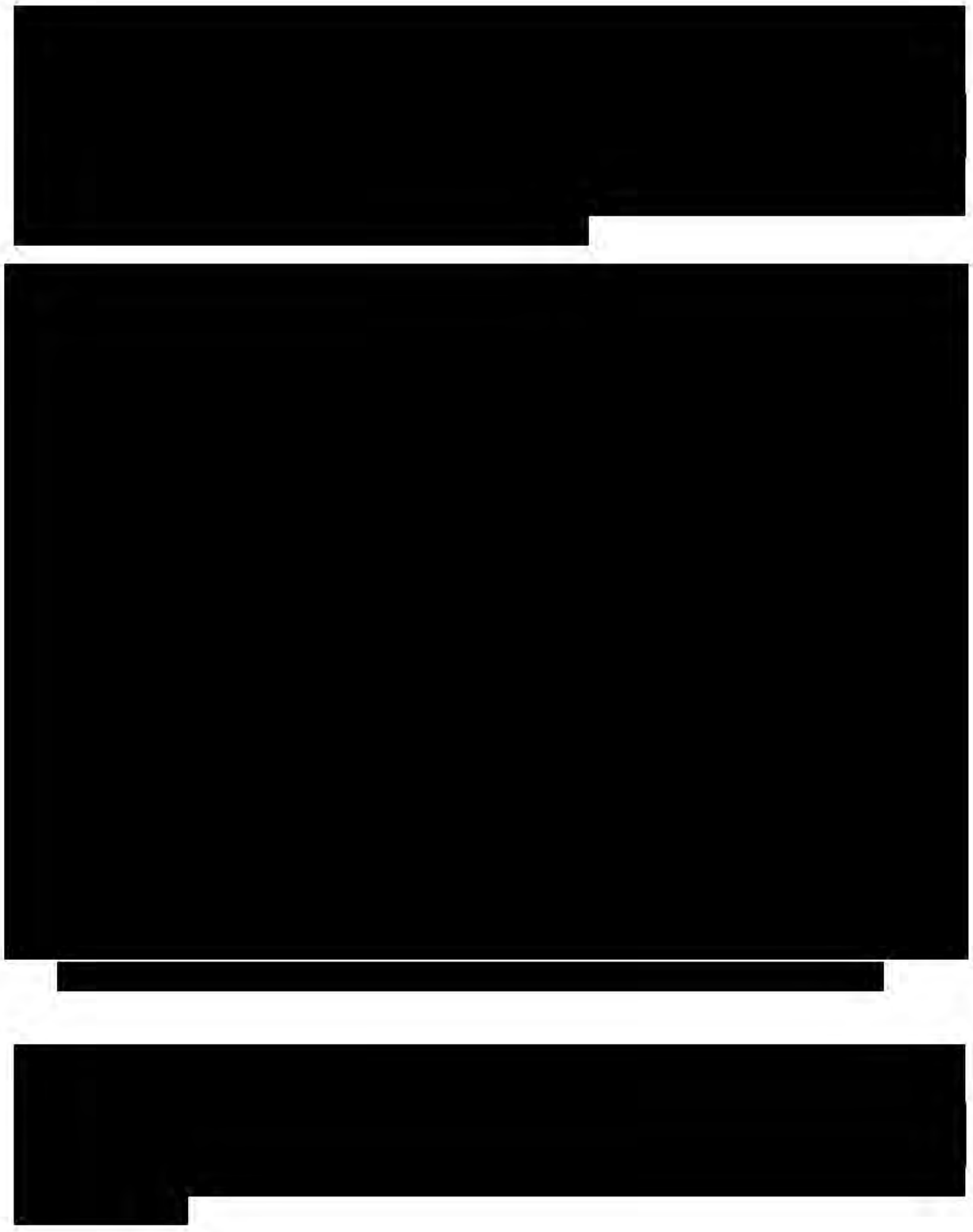

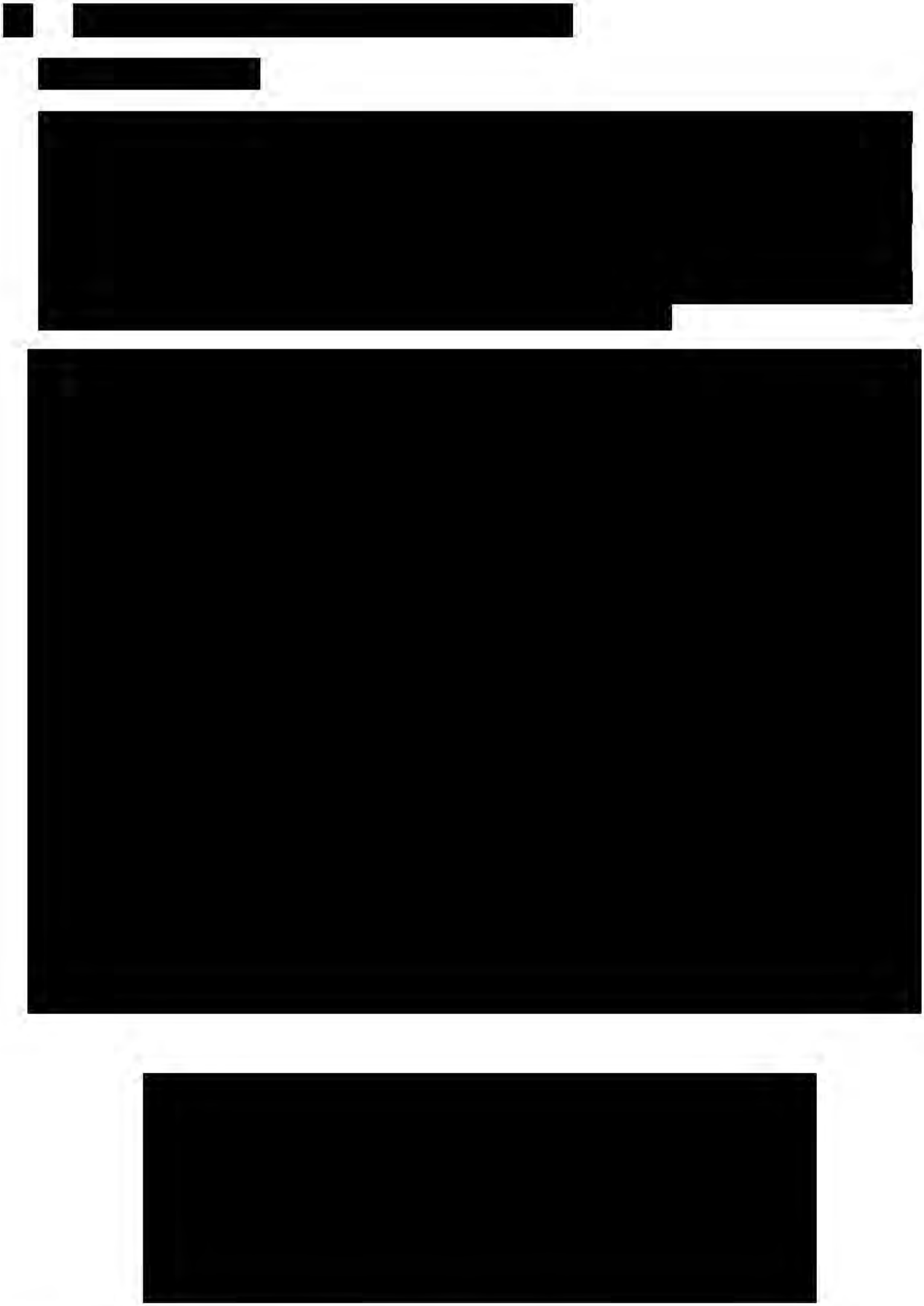

[redacted]

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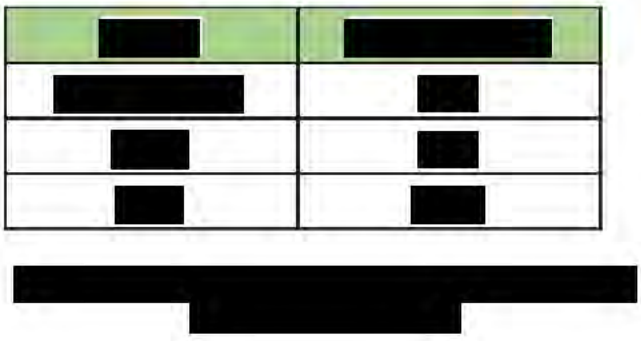

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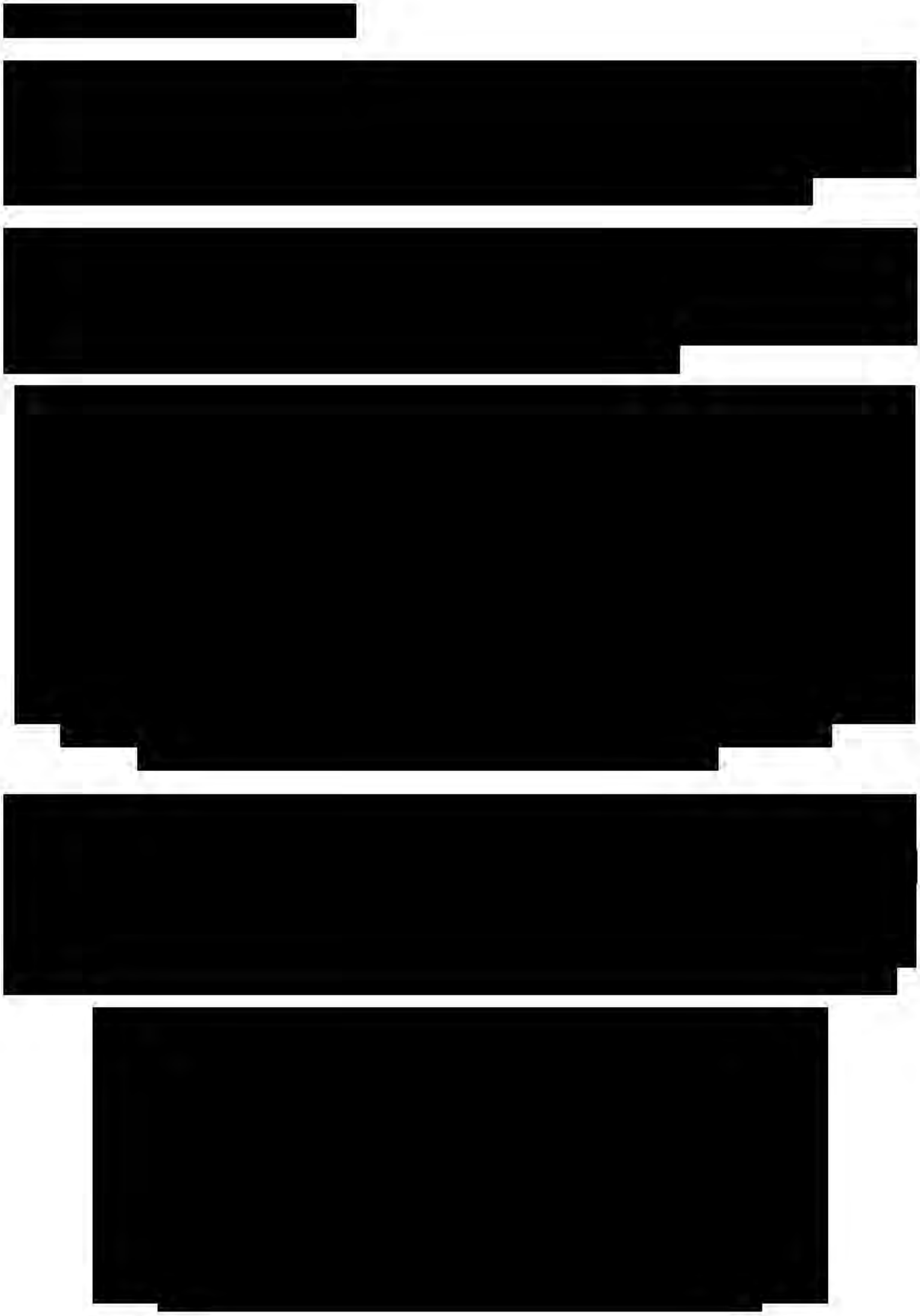
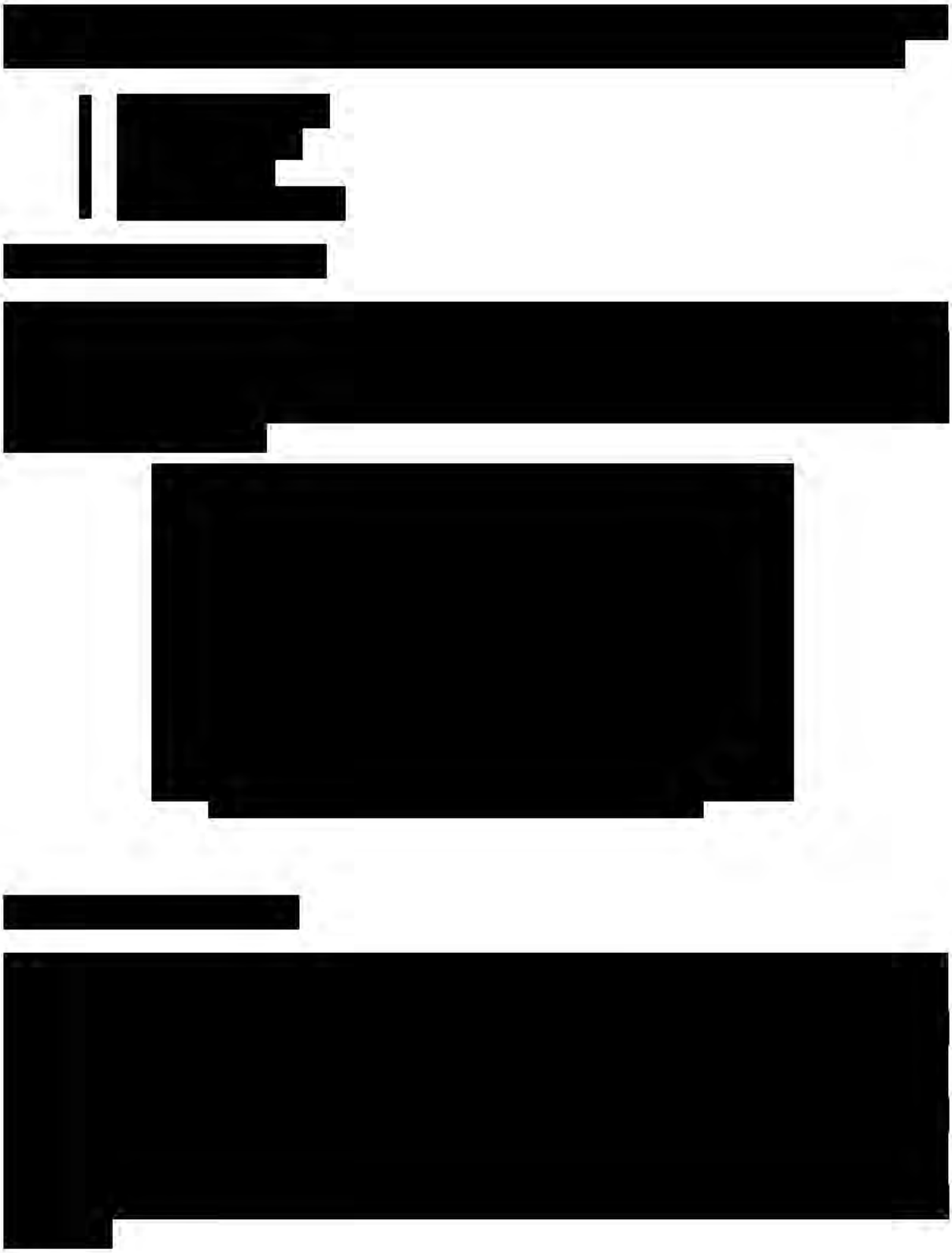
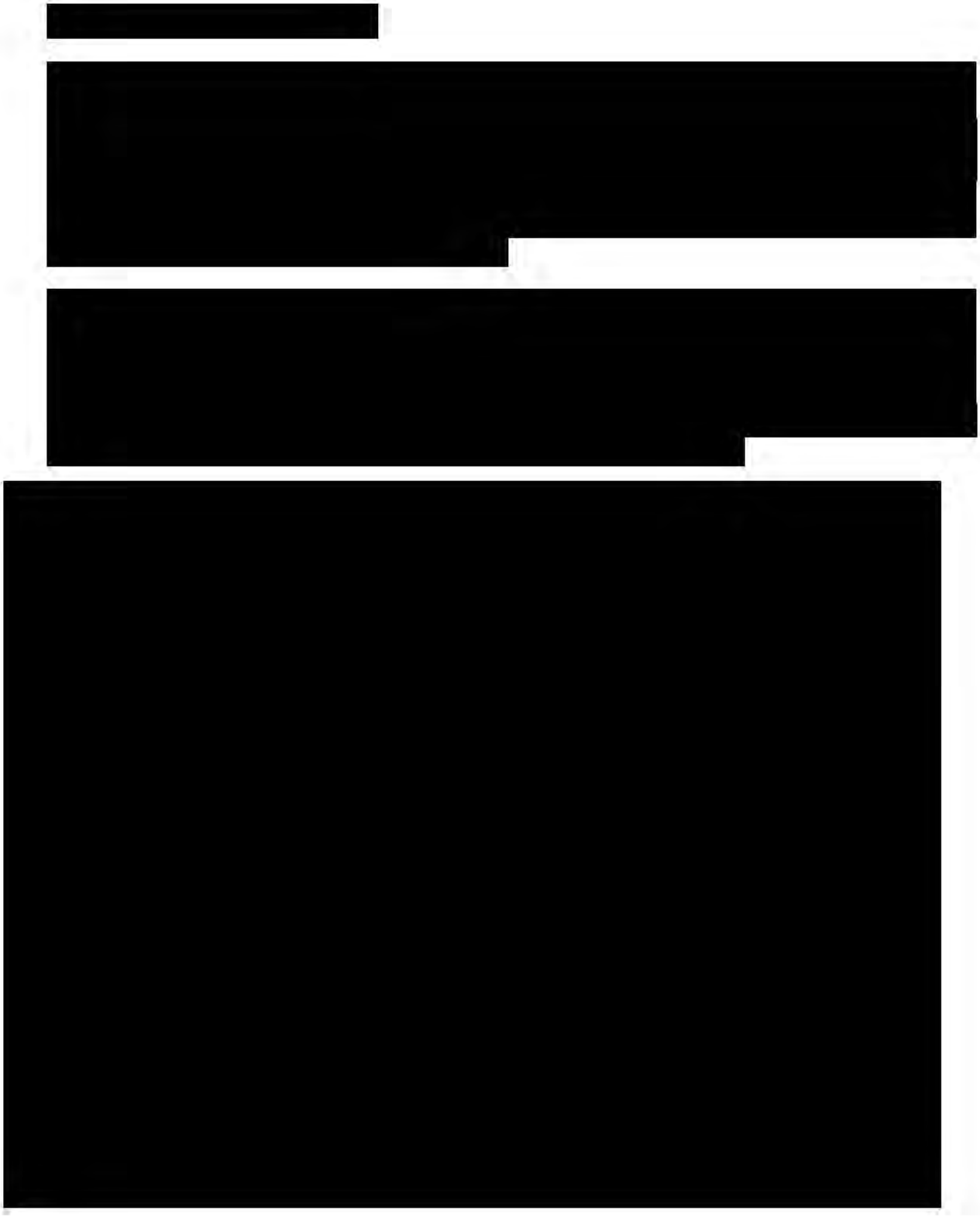
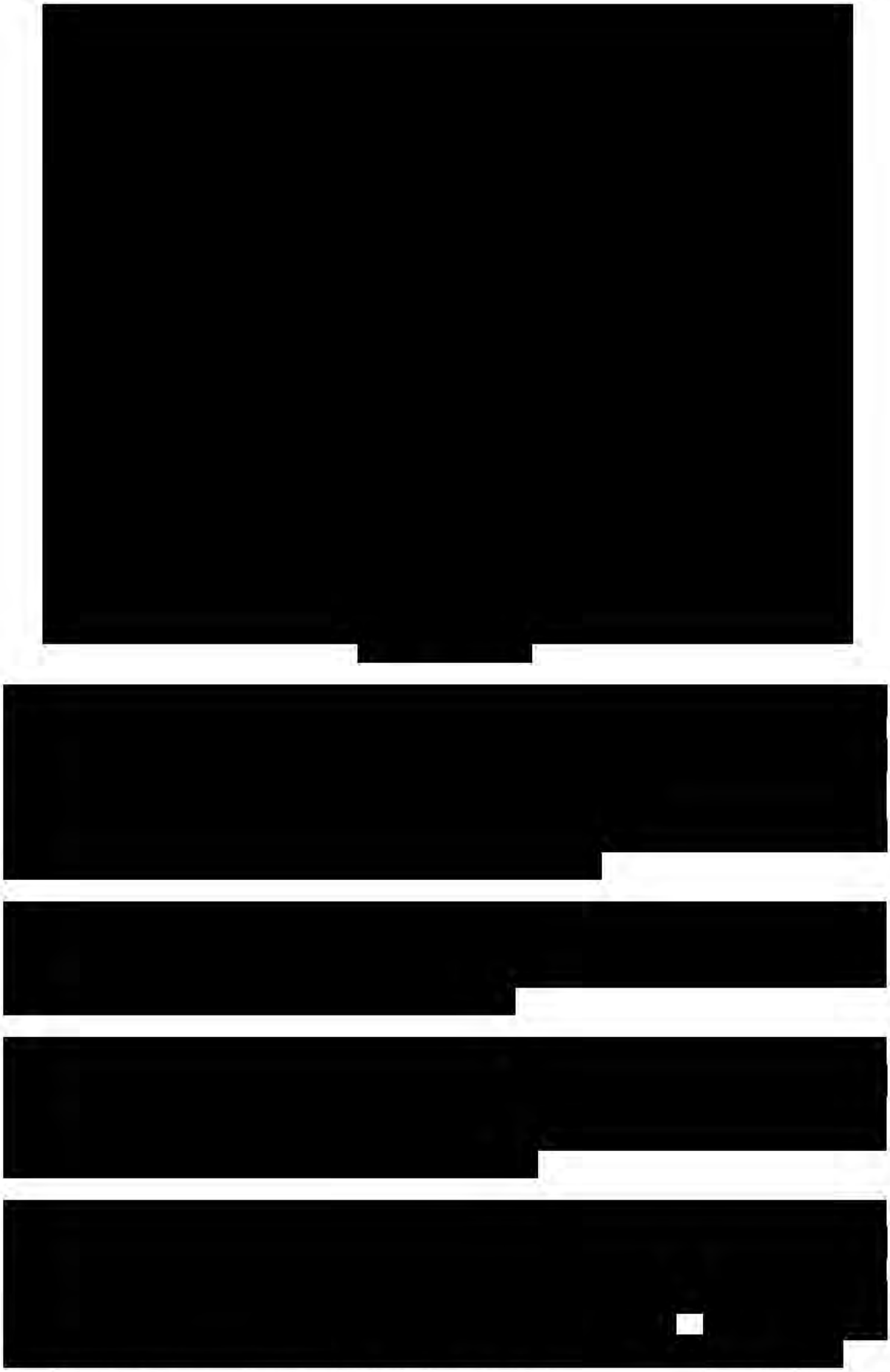
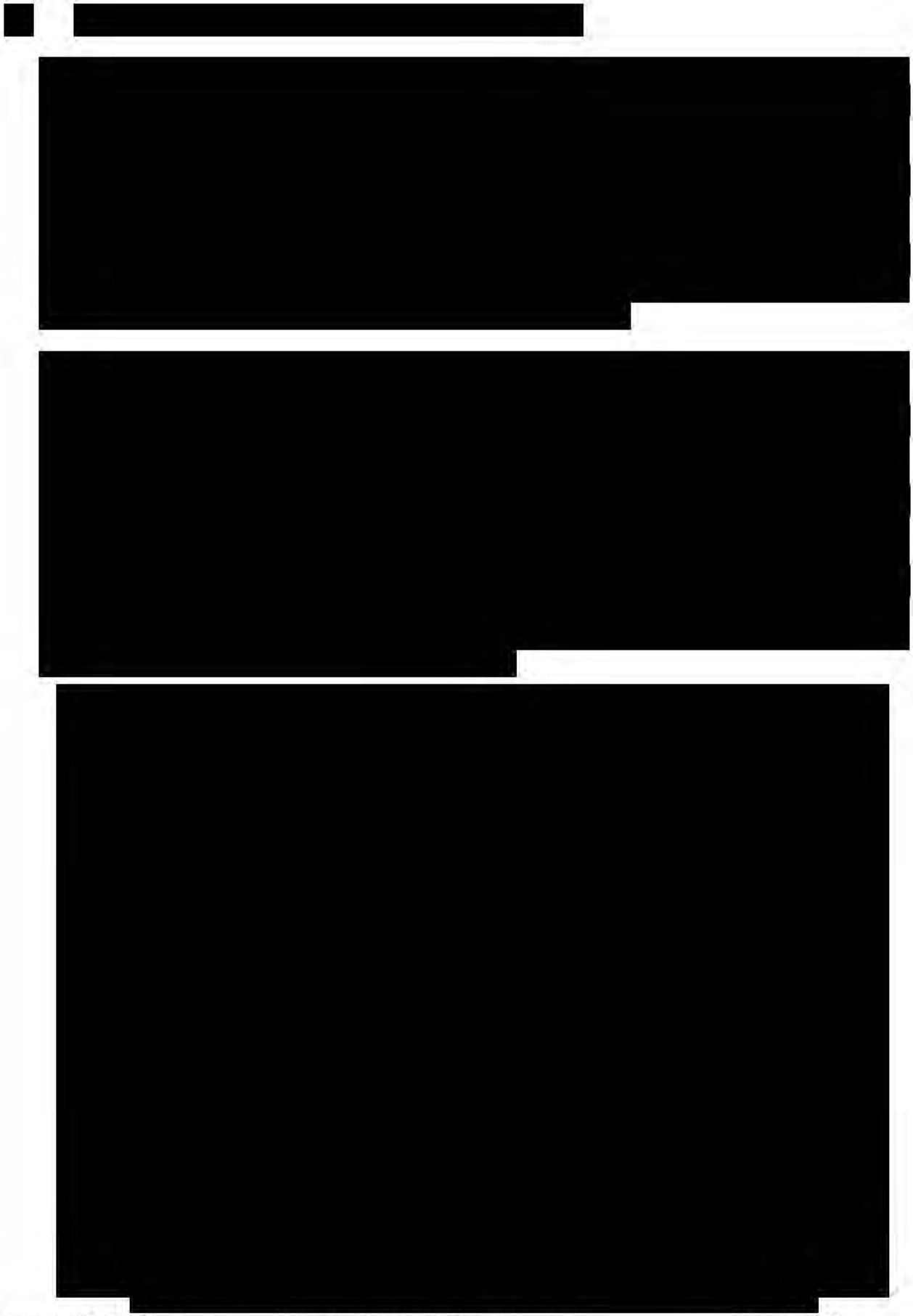
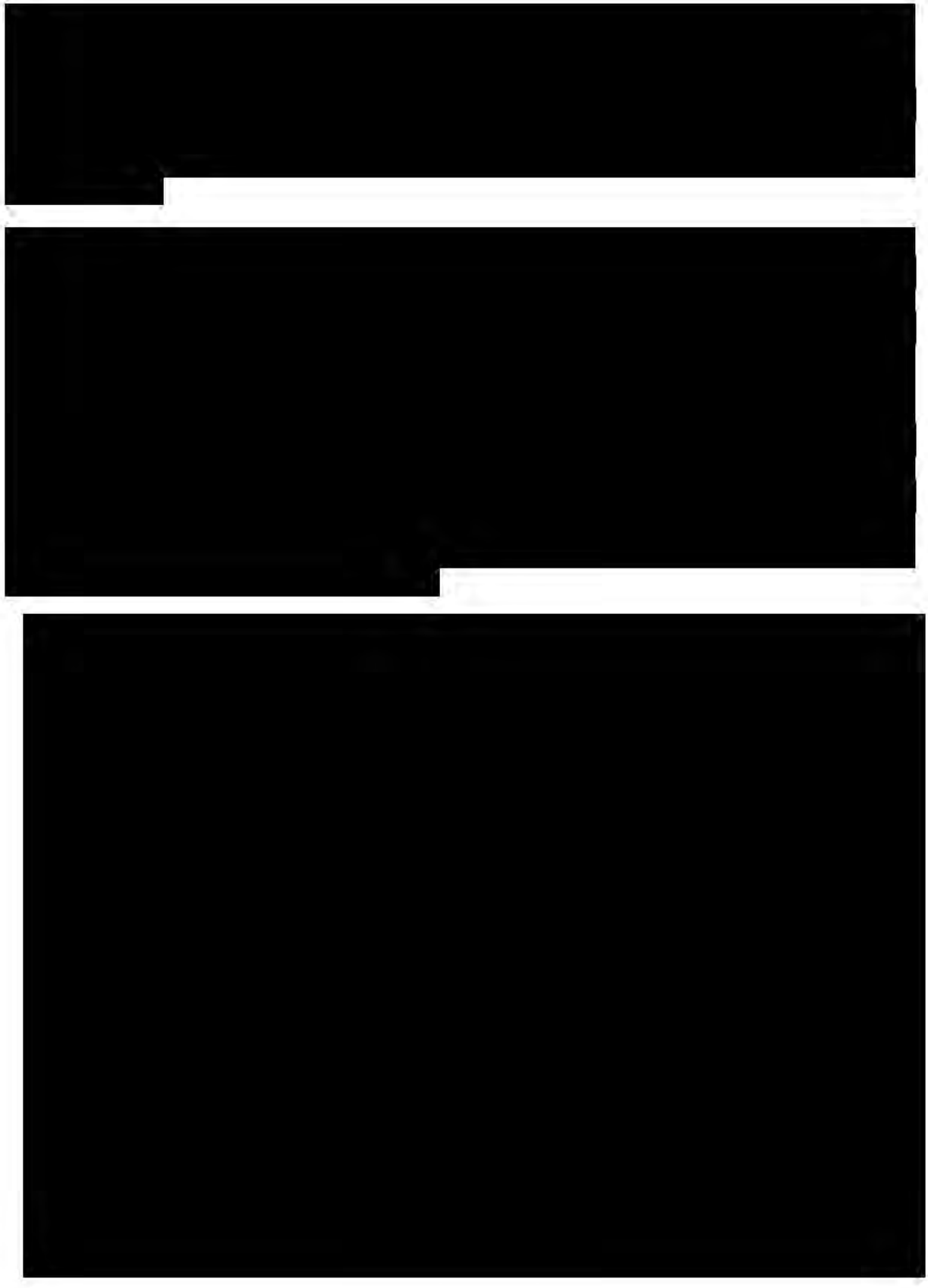






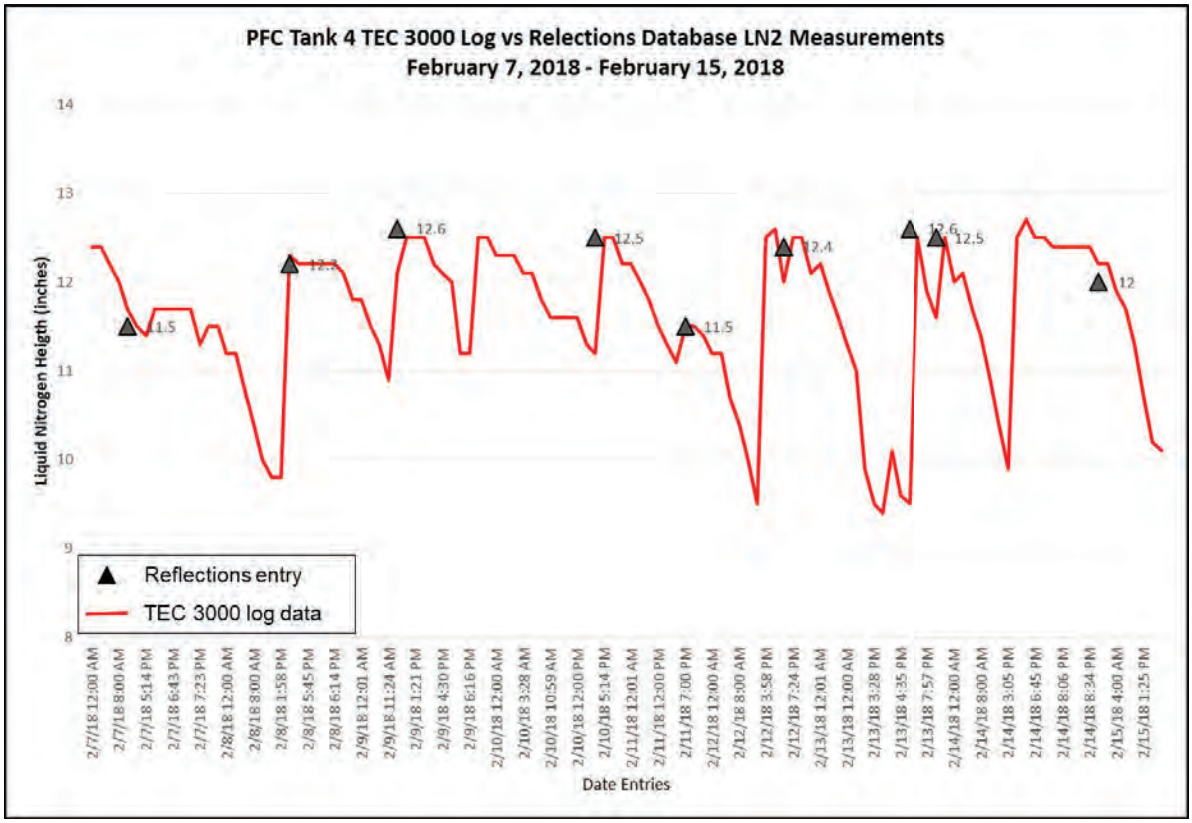






I have analyzed and compared data records available from the subject TEC 3000 controller download and the PFC Reflections database for the month of February 2018 through the incident of March 4, 2018. This comparison reveals that the method of recording LN2 levels was insufficient for accurately monitoring LN2 usage levels. Greater awareness of the changing LN2 usage level by the PFC staff could have alerted them to an impending problem with the MVE 808 Tank 4 system.

Dr. Conaghan, when asked in his deposition about the frequency of checking the Tank 4 usage rate, responded, "We didn't check usage." The recording method employed by PFC staff as described in deposition testimony by Dr. Conaghan and PFC Embryologist G. Cirimele stated that recordings were made after checking and filling Tank 4 both before the incident of February 15, 2018 and after that until March 4, 2018. By recording the level of LN2 only after the fill operation, the records will always show a "full" level. An alternative would be to check and record the level of LN2 prior to filling and after completion of the filling operation. This would provide an indication of how much LN2 was being depleted between fillings (usage rate) and serve as an indicator if problems were developing with the tank. An overlay of data leading up to the incident of February 15, 2018 shown in the plot below illustrates how the consistent data of the once-a-day fill level record obscures the fact that the rate of LN2 level change (usage) is very dynamic. In addition, overlooking this parameter was compounded by the configuration setting to not display the usage level value.



PFC Tank 4 TEC 3000 LN2 levels recorded from February 7 through February 15, 2018 shown with the red trace. The triangle symbols denote the Reflections data entered by PFC staff at the end of each day.

5.8 Chart MVE TEC 3000 troubleshooting corrective action procedures

I have reviewed Chart documentation describing recommendations for MVE TEC 3000 preventive maintenance and troubleshooting steps in the event of abnormal operation. Various operational symptoms are cross referenced with possible causes, fixes, and instructions on how to implement or execute the recommended fix. The TEC 3000 controller includes alarms to alert for several of these abnormal conditions. The cross referenced fix recommendations and instructions are an outcome of the failsafe design analysis. The directive to seek help by reporting technical issues to an MVE distributor or technical service are ultimately noted in the event that recommended fixes leave the issue unresolved.

Depositions referenced by Chart engineers R. Gonzalez, B. Wade, and J. Junnier make reference to procedures adopted by Chart to perform troubleshooting of MVE TEC 3000 field issues. When notified of field issues such as Serial Number equal to 0, LN2 level equal to 0, or tanks not filling, customers were notified and instructed with guidelines to troubleshoot. A Return Material Authorization or RMA process within Chart managed customer returns of TEC 3000 controller units resulting in customers receiving either repaired or replacement TEC 3000 units. In some cases, Chart personnel would work with controller manufacturer Extron to identify the root cause of certain TEC 3000 issues.

The event history download from the subject controller indicates that alarms on the afternoon of February 15, 2018 were accompanied by a power interruption or PF event. Prior to this the system had been commanded to Fill and LN2 level measured at 10.2 inches. Per deposition testimony from Dr. Conaghan, “My decision was to turn off the controller because it was in a constant state of alarm.” The low level alarm and LN2 reading of 0.0 inches combined with visual observation that LN2 was at an appreciable level as discerned by manual measurement should have been an indication that the TEC 3000 LN2 level measurement was not working properly. Chart had preventative maintenance recommendations, troubleshooting guidelines and product return and replacement procedures in place. If PFC had notified Chart of the incident of February 15, 2018 then troubleshooting would have been initiated resulting in repair or replacement of the subject TEC 3000 controller. Instead, the decision by PFC was to unplug the controller and resort to manual fill and monitoring procedures.

6. Discussion of Opinions

I have formed the following opinions as a result of my analysis and investigation of the Chart MVE 808 TEC 3000 Controller system and including the subject PFC Tank 4 TEC 3000 controller involved in the incident of March 4, 2018. I have reached the following opinions to a reasonable degree of engineering certainty.

[redacted]

5. PFC personnel did not notify Chart immediately after the incident on February 15, 2018 resulting in the subject TEC 3000 controller entering a constant state of alarm. Chart would have proceeded with troubleshooting recommendations and service or return procedures if notified by PFC promptly.

   - Chart documentation and correspondence outline steps recommended for troubleshooting TEC 3000 controller issues.
   - PFC response to TEC 3000 abnormal operation observed initially on February 15, 2018 was to unplug the controller.

6. The manual monitoring method employed by PFC before and after the event involving the subject controller on February 15, 2018 was insufficient to accurately monitor and record LN2 usage levels during this period of operation.

   - The PFC procedure to recording the LN2 level after the fill operation will always create a record showing that Tank 4 is at its "full" or target level around 12.5 inches.
   - This method does not capture how much LN2 was depleted (usage rate) between fill operations, which would indicate potential problems.

- Recording the LN2 prior to and after the fill operation would be more effective in monitoring LN2 usage rate.

7. Conclusions

[redacted]

These opinions are expressed with a reasonable degree of engineering certainty based on my engineering educational background, industry affiliation, and development and design experience of control systems. I reserve the right to revise these opinions and offer new opinions as additional information becomes available. Finally, I may use any or all of the materials listed in Attachments A and B as exhibits, if needed, at the time of trial.

Sincerely,

Eldon G. Leaphart

Attachment A

Materials Received in In re Pacific Fertility Center

Pleadings

- 2020-07-13 Download File Materials *(926 document files)*

1. PFC Plaintiff Complaint
2. Third Amended Complaint

Discovery

- 2020-07-13 Download File Materials *(187 document files)*

Deposition Transcripts

- 2020-07-13 Download File Materials *(531 document files)*
- 2020-09-30 Download File Materials *(221 document files)*

3. Christine Allen
4. Jennifer Andres
5. Barry Behr
6. Frank Bies
7. Christopher Brand
8. Jeff Brooks
9. Katherin Buchanan
10. Philip Chenette
11. Gina Cirimele
12. Joseph Conaghan
[redacted]
14. Jeffery Dresow
[redacted]
16. Erin Fischer
17. Carolyn Givens
18. Ramon Gonzalez
19. Keith Gustafson Vol. 1
20. Keith Gustafson Vol. 2
21. Jinnuo Han
22. Carl Herbert
23. Susan Hertzberg
24. Allison Hubel
25. Heather Huddleston
26. Nicholas Jewell
27. Justin Junnier
28. Anand Kasbekar
29. Liyun Li
30. Shuangge Ma
31. Greg Mueller

[redacted]
34. William Pickell
35. Jean Popwell
[redacted]
37. Alden Romney
38. Isabelle Ryan
39. Eldon Schriock Vol. 2
40. Eldon Schriock Vol. 3
41. Arun Sharma
[redacted]
43. Stephen Somkuti
44. Duane Steffey
45. Brendon Wade

Chart Document Production

- 2020-07-13 Download File Materials *(2977 document files)*
- 2020-09-16 Download File Materials *(2 document files)*

46. Chart MVE 808 - TEC 3000 Engineering Drawings; Bates Ref: CHART000061-000077, CHART 000078-000126
47. TEC 3000 Data Download #1; Bates Ref: CHART000127
48. TEC 3000 Data Download #2 and #3; Bates Ref: CHART070093 & CHART070095
49. MVE TEC 3000 Operation and Maintenance Manual; Bates Ref: CHART000701-000860
50. Chart FMEA Materials; Bates Ref: CHART001432
51. Chart MVE-TEC 3000 Functional Test; Bates Ref: CHART044297-044317
52. Intertek Chart EMC Test Report; Bates Ref: CHART037672-037747
53. Chart TEC 3000 Firmware Version 2.02 Engineering Test Report; Bates Ref: CHART014175-014254

Expert Reports

- 2020-07-13 Download File Materials (*15 document files*)

54. Christopher Brand
55. Keith Gustafson
56. Anand Kasbekar PhD

Other Party Documents

- 2020-07-13 Download File Materials (*3050 document files*)

57. Extron DFMEA; Bates Ref: EXTRON005744
58. CAP Submitted Report 2018-03-23; Bates Ref: MSO000081-MSO000088
59. Maintenance Records for Storage Tanks; Bates Ref: MSO000094-MSO000147
60. Tank 4 Photos; Bates Ref: MSO026714-MSO026778

61. Overnight Usage Chart Tank 1 – Tank 8; Bates Ref: MSO011014

Miscellaneous

- 2020-09-16 Download File Materials (*1 document file*)
- 2020-09-17 Download File Materials (*1 document file*)

62. Chart TEC 3000 Firmware Version 2.01
63. Chart TEC 3000 Firmware Version 2.05

Attachment B

Materials Reviewed or Generated for In re Pacific Fertility Center

1. CV – Eldon G. Leaphart
2. Testimony List – Eldon G. Leaphart
3. Deposition summaries
4. Photographs, video, notes, and measured data – Carr Engineering, Inc., PFC Component Inspection, September 28, 2020
5. Photographs – Carr Engineering, Inc., Exemplar TEC 3000 Controller Photos, September 28, 2020
6. Data – Carr Engineering, Inc., Exemplar TEC 3000 Controller Download Data, October, 2020
7. Data – Carr Engineering, Inc., Exemplar TEC 3000 Measurement Data, October 2020
8. Data – Carr Engineering, Inc., Subject TEC 3000 Log Data Analysis, October 2020
9. Datasheet – MDL-20464 Display Driver IC
10. Datasheet – MPX10DP Pressure Transducer IC
11. Datasheet – PIC 18F6722 Microcontroller Datasheet
12. Datasheet – PN 14224611S Solenoid Valve
13. Datasheet – PN 13284954S Purge Solenoid Valve
14. Manual – Fluke 712 RTD Calibrator Manual
15. Manual – Fluke 719 Pro Pressure Calibrator Manual
16. Manual – Lakeshore Cryogenic Model 336 Manual
17. Manual – Themo Scientific Model 7400 Series Operating Manual
18. Brochure – Themo Scientific Cryopreservation Storage Equipment
19. Manual – Themo Scientific Model ULT Series Operating Manual
20. Brochure – Cryologic Freeze Control Freezer Systems Brochure
21. Manual – Planer Model 300 and 500 Series Manual
22. Manual – Themo Scientific Cryoextra CE8100 Operating Manual
23. Manual – Sensaphone Sentinel Operating Manual
24. Excerpt – IEC 61000-6-4 EMC Generic Standards, edition 3.0
25. Excerpt – IEC 60601-1-2 Medical Electrical Equipment, edition 4.0

Attachment C

Curriculum Vitae for Eldon G. Leaphart

Eldon G. Leaphart
- Bachelor of Science – Electrical Engineering, The Ohio State University (1987)
- Master of Science – Electrical Engineering; Control Systems, The Ohio State University (1991)

Specialized Professional Competencies
- Specification, design, test, and evaluation of electro-mechanical control systems for motor vehicles including powertrain, safety, steering, handling, and braking systems
- Specification, design, test, and evaluation of embedded software for motor vehicles including sensor processing, diagnostic and countermeasure implementation, serial communications, and control algorithms
- Design and implementation of automotive functional safety processes and software design consistent with ISO-26262 (Functional Safety for Road Vehicle Standard)
- Development of software requirements management, software architecture specification, model-based software design, and ASPICE (Automotive Software Process Improvement Capability dEtermination)

Professional Experience and Qualifications
- Product Engineer, Controlled Suspensions, Delco Products (1987 – 1989)
- Graduate Student (GM Fellowship) College of Engineering, The Ohio State University (1989 – 1991)
- Algorithm Engineer, Chassis/Suspension Integration, Chassis Systems Center (1991 – 1993)
- Application Engineer, Stability Control, Delphi Energy & Chassis (1993 – 2000)
- Algorithm Engineer, Stability Control Sensors, Delphi Energy & Chassis (2000 – 2003)
- Brake Controls Software Architect, Delphi Energy & Chassis (2003 – 2004)
- Engineering Manager, Diagnostics and Serial Communications, Delphi Chassis (2004 – 2008)
- Engineering Manager, Software and Systems Group, Delphi Chassis / BWI (2008 – 2016)
- Principal Engineer, Carr Engineering, Inc. (2016 – Present)

Publications and Achievements
- Master's Thesis: A DSP Hybrid Simulator For Evaluating Anti-Lock Brake System Control Designs, The Ohio State University (1991)
- Technical Publication: Survey of Software Failsafe Techniques for Safety Critical Automotive Applications, SAE International (2005)
- Technical Publication: Application of Robust Engineering Methods to Improve ECU Software Testing, SAE International (2006)
- Technical Presentation: Evolving OEM / Supplier Relationships Relative to System Design Satisfying ISO-26262, Car Training Institute (2012)
- Technical Presentation: Application of ISO-26262 "Confidence In Use Criteria" Toward ECU Software Development Tool Workflow, dSPACE Technical Conference (2013)
- Technical Presentation: The Next Frontier: Investigating The Alleged Vehicle "Software" Failure Claim, ABA Emerging Issues In Motor Vehicle Product Liability Litigation (2016)
- Technical Presentation: ISO 26262 Part 8: Supporting Processes, IQPC USA ISO 26262 Conference, (2017)
- Instructor SAE Course C1704: ADAS Application – Automatic Emergency Braking (2017)
- Competition Report Judge Formula SAE Collegiate Failure Mode Effects Analysis Exercise (2019 – Present)
- Recipient of seven US Patent Awards
- Recipient of GM President's Council Award: Automotive Chassis Control (1996)
- Recipient of two GM Boss Kettering Awards: Automotive Chassis Control – Integrated Chassis (1996) and Unified Brake and Suspension Control, Suspension & Steering (2000)

Technical Committees / Industry Affiliations
- SAE International – Member
- US Technical Advisory Group to ISO TC22/SC3/WG16 Functional Safety Committee
- INCOSE (International Counsel on System Engineering)

Attachment D

Testimony Record for Eldon G. Leaphart

Case Name	Case #	Venue	Type	Date
Bernardino v Nissan	BC 493949	Superior Court of CA, County of Los Angeles – Central	Deposition	06/02/2017
Bernardino v Nissan	BC 493949	Superior Court of CA, County of Los Angeles – Central	Trial	07/13/2017
Slayen v Mercedes-Benz USA, LLC	BC 633726	Superior Court of CA, County of Los Angeles – Stanley Mosk Courthouse	Deposition	02/28/2018
Slayen v Mercedes-Benz USA, LLC	BC 633726	Superior Court of CA, County of Los Angeles – Stanley Mosk Courthouse	Trial	03/26/2018
Makhlouf v Nissan	CL15-3214-00	Circuit Court for the City of Virgina Beach	Deposition	07/13/2018
Pahan v Kia	2014 L 004163	Circuit Court of Cook County Illinois County Department	Deposition	09/06/2018
Pahan v Kia	2014 L 004163	Circuit Court of Cook County Illinois County Department	Trial	10/04/2018
Hill / Parks v Kia	4:16-cv-117	United States District Court Eastern District of Tennessee at Winchester	Deposition	04/24/2019
Bicknell v GM	50-2011 CA 003575 XXXX MB AA	Circuit Court of the Fifteenth Judicial Circuit in and for Palm Beach County Florida	Deposition	05/15/2019 06/18/2019
Stroud v Kia	Case No. BC705872	Superior Court of California, County of Los Angeles – Central	Deposition	12/30/19

Stroud v Kia	Case No. BC705872	Superior Court of California, County of Los Angeles – Central	Trial	02/05/20